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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,425	11/29/2001	Shlomit R. Edinger	21402-175 CIP (Cura-475 C	6437

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,425	EDINGER ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 38 and 41, drawn to drawn to an isolated polypeptide comprising the amino acid sequence set forth as SEQ ID NO:2, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54 or 56, pharmaceutical compositions and kits comprising said isolated polypeptide, classified in class 530, subclass 350.

II. Claims 5-14, 39 and 42 drawn to an isolated nucleic acid molecule encoding the amino acid sequences set forth as SEQ ID NO: 2, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54 or 56 and variants thereof, and a vector, host cell, pharmaceutical composition and kit comprising said isolated nucleic acid, classified in class 536, subclass 23.5.

III. Claims 15-17, 40 and 43, drawn to an antibody that binds the amino acid sequence set forth as SEQ ID NO: 2, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54 or 56, and a pharmaceutical composition and kit comprising said antibody, classified in class 530, subclass 387.9.

IV. Claims 18, 44 and 45, drawn to a method of determining the presence or amount of a polypeptide comprising introducing an antibody that binds immunospecifically to the polypeptide of Group I, classified in class 435, subclass 7.1.

V. Claims 19-21, 46 and 47, drawn to a method of determining the amount or presence of the nucleic acid molecule comprising introducing a probe that binds to the nucleic acid molecule of Group II, classified in class 435, subclass 6.

VI. Claims 22 and 23, drawn to a method of identifying an agent that binds to the polypeptide of Group I comprising introducing said polypeptide, classified in class 435, subclass 4.

VII. Claims 24 and 25, drawn to drawn to a method for identifying a potential modulator of the polypeptide of Group I, and method of using said modulator, comprising providing a cell or animal expressing the polypeptide of Group I, classified in class 435, subclass 4.

VIII. Claims 26-29 and 48, drawn to a method of treating or preventing a pathology comprising administering the polypeptide of Group I, classified in class 530, subclass 350.

IX. Claims 30-33, drawn to a method of treating or preventing a pathology comprising administering the nucleic acid of Group II, classified in class 514, subclass 44.

X. Claims 34-37 and 49, drawn to a method of treating of preventing a pathology comprising administering the antibody of Group III, classified in class 530, subclass 387.9.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acid of Invention II is related to the protein of Invention I by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein

in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The polypeptide of Inventions I is related to the antibody of Invention III by virtue of binding affinity. Although the polypeptides and antibodies are related since the antibody binds to the polypeptide and can be raised by immunization with the polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be made obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the polypeptide may be used for processes other than the production of the antibody, such as a standard in an assay for the presence of the protein.

The nucleic acid of Inventions II is related to the antibody of Invention III by virtue of the antibodies' binding affinity for a protein encoded by the nucleic acid. Although the nucleic acids and antibodies are related via the polypeptide encoded by the nucleic acids, which binds to the antibodies and can be used to make the antibodies by immunization, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be made obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides.

Further, the nucleic acid may be used for processes other than the production of the protein, such as a nucleic acid hybridization assay.

Inventions VI and VIII are distinct methods of using the polypeptide of Group I. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to a method of identifying an agent that binds to a polypeptide and a method of treatment. The methods are not disclosed as capable of use together in a single process and, clearly, each of these methods would have very different modes of operation and effect, as the method of identifying an agent that binds to a polypeptide would comprise steps for determining binding that would not be comprised in the method of treatment. Likewise, the method of treatment would comprise administration steps and monitoring steps that would not be comprised in a method of identifying an agent that binds.

Invention I is related to Invention VI and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in each of the materially different processes of inventions VI and VIII.

Inventions V, VII and IX are directed to distinct methods of using the nucleic acid of Invention II, which methods are not disclosed as capable of use together in a single process. Invention V is directed to a method that would comprise nucleic acid hybridization, Invention

VII is directed to a method that would comprise expression of a polypeptide from the polynucleotide and Invention IX is directed to a method of treatment, which would comprise administering the polypeptide to a patient in need thereof. Thus, each of these methods would clearly comprise modes of operation and functions not comprised by the others. In addition each of the methods has distinct effects (i.e. diagnostic versus discovery versus therapeutic).

Inventions IV and X are directed to distinct methods of using the antibody of Group III. The different inventions are directed to a method of determining the presence or amount of a polypeptide and a method of treatment. The methods are not disclosed as capable of use together in a single process and, clearly, each of these methods would have very different modes of operation and effect, as the method of determining the presence or amount of a polypeptide would comprise steps for measuring antibody binding that would not be comprised in the method of treatment. Likewise, the method of treatment would comprise administration steps and monitoring steps that would not be comprised in a method of determining the presence or amount of a polypeptide.

Invention II is related to invention V, VII and IX, and Invention III is related to Invention IV and X as product and process of use. Again, in each case the products can be used in the materially different processes to which the method Groups are drawn.

Each of the methods, Groups VI and VIII, Groups V, VII and IX and Groups IV and X are distinct, each from the other. The different inventions are not disclosed as capable of use together and have different modes of operation as evidenced by their use of patentably distinct products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

Each group set forth above is further restricted to a single polypeptide comprising or nucleic acid encoding a sequence set forth as SEQ ID NO: 2, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54 or 56. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Similarly, proteins comprising unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
February 4, 2004

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER